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10/583,036	07/25/2007	Pietronella Christina Ladru	2001-1450	6754
<div>466 7590 11/24/2009</div> <div>YOUNG & THOMPSON 209 Madison Street Suite 500 Alexandria, VA 22314</div>				
EXAMINER				
CHU, KAI-YIU K				
ART UNIT		PAPER NUMBER		
4177				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary

Application No.

10/583,036

Applicant(s)

LADRU ET AL.

Examiner

KAIYEU CHU

Art Unit

4177

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-18 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 15 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 06/15/2006
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. In response to the Preliminary Amendment filed on June 15, 2006, claims 1-18 are pending.

Information Disclosure Statement

2. Applicant is informed that the World document WO 96/2727404 cited on the information disclosure statement filed June 15, 2006 has been corrected as --WO 96/27404--, so as to overcome the typographic error. No further action is required.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "37" has been used to designate both "a space" and "a tubular section"; and reference characters "6" and "15" have both been used to designate "the oesophagus". Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities: The terms “stiffener 2” (Pg. 7, line 12) and “strip 19” (line 19) should be respectively recited as --stiffener 10-- and --strip 9--, so as to overcome the typographic error. In addition, the description of the reference number “13” in Fig. 2 is missing. Appropriate correction is required.

Claim Objections

5. Claim 6 is objected to because of the following informalities: The term “approximately 6cm” should be recited as --approximately 6 cm--, so as to clarify the typographic error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 10, the phrase “such as” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 13, the antecedent basis for “the flexible stiffener” has not been clearly set forth.

Regarding claim 18, the recitation therein is unclear and confusing. It is not understood as to whether it is an independent claim or dependent claim. If it is an independent claim, then all the needed structural elements must be clearly set forth thereto. If it is a dependent claim, then the preamble is inconsistent. In addition, the phrase “such as” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-8, 11, 14 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bronson et al. (US Pat. No. 4,327,720).

Regarding claim 1, Figs. 1 and 6-12 of Bronson et al. teaches respirator for a person or animal comprising a tube assembly (10) that is intended to be fed via the mouth and the pharynx towards the trachea (see Fig. 6) and an inflatable cuff (15b) that is provided at the distal end of the tube assembly, the cuff being equipped to form a seal between the wall of the tube assembly and a wall of the pharynx when it is in the inflated state (see Fig. 8), the tube assembly having a first tube part (9) and the tube assembly having a length suitable for bringing the distal end of the first tube part to the entry to the trachea while the proximal end of the tube assembly is outside the mouth (see Fig. 10). It is noted that Bronson et al. does not teach that the cuff has a distal cuff part intended to extend into the oesophagus and, in the inflated state, to close off the oesophagus, and in that the distal cuff part has a constriction zone which, in the inflated state, provides a constriction in the distal cuff part. However, Bronson et al. teaches a second cuff (15a) that extends into the oesophagus and, in the inflated state, closes off the oesophagus (see

Fig. 10), and in that the distal cuff part has a constriction zone which, in the inflated state, provides a constriction in the distal cuff part (Fig. 10 shows cuff 15a being constricted by the esophagus). Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine cuffs 15a and 15b into a single cuff in order to form a single seal against the walls of the body rather than two separate seals.

Regarding claim 2, it is noted that Bronson et al. does not explicitly teach that the constriction zone has a length of 1 to 4 cm. However, Bronson et al. also does not mention any length for the constriction zone but the device of Bronson et al. could very well have a constriction zone with a length of 1 to 4 cm in order to properly fit the esophagus of a patient. Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a constriction zone length of 1 to 4 cm in the device of Bronson et al. in order to properly fit the cuff into a patient.

Regarding claim 3, Bronson et al. teaches that the distal part of the cuff has, distal to the constriction zone, a section that is tubular in the inflated state (see Figs. 8-11).

Regarding claim 4, it is noted that Bronson et al. does not explicitly teach that the tubular section has a length of 1.5 to 10 cm. However, Bronson et al. also does not mention any length for the tubular section but the device of Bronson et al. could very well have a tubular section length of 1.5 to 10 cm in order to properly fit the esophagus of a patient. Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a tubular section length of 1.5 to 10 cm in the device of Bronson et al. in order to properly fit the cuff into a patient.

Regarding claim 5, it is noted that Bronson et al. does not teach that the length of the tubular section is longer than approximately 2 cm. However, Bronson et al. also does not explicitly mention any length for the tubular section but the device of Bronson et al. could very well have a tubular section length of longer than approximately 2 cm in order to properly fit the esophagus of a patient. Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a tubular section length of longer than approximately 2 cm in the device of Bronson et al. in order to properly fit the cuff into a patient.

Regarding claim 6, it is noted that Bronson et al. does not explicitly teach that the length of the tubular section is shorter than approximately 8 cm and is preferably shorter than approximately 6 cm. However, Bronson et al. also does not mention any length for the tubular section but the device of Bronson et al. could very well have a tubular section length of shorter than approximately 8 cm and preferably shorter than approximately 6 cm in order to properly fit the esophagus of a patient. Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a tubular section length of shorter than approximately 8 cm and preferably shorter than approximately 6 cm in the device of Bronson et al. in order to properly fit the cuff into a patient.

Regarding claim 7, Bronson et al. teaches that the tube assembly has a second tube part (11) with a length suitable for introducing the distal end of the second tube part into the oesophagus whilst the proximal end of the second tube part is outside the mouth (see Fig. 10).

Regarding claim 8, Bronson et al. teaches that the cuff is provided around the distal end of the tube assembly and in that the distal end of the second tube part extends through the cuff in a sealed manner (see Fig. 10).

Regarding claim 11, Bronson et al. teaches that the inside of the second tube part has a circular cross-sectional shape (see reference 11' in Fig. 13).

Regarding claim 14, Bronson et al. teaches that the cuff, or at least a proximal part thereof, is so fitted asymmetrically on the tube assembly and also has such a shape that, when the proximal part of the cuff is in the inflated state in the pharynx, the proximal part of the cuff essentially fills the pharynx and pushes the distal orifice of the first tube part (9) in front of the entry to the trachea (see Fig. 10).

Regarding claim 16, it is noted that Bronson et al. does not specifically teach that the interior of the proximal part of the cuff is in fluid communication with the interior of the remainder of the cuff, such that, in the inflated state, the same pressure prevails throughout the cuff. However, a single cuff would inherently be in fluid communication with itself and it is well-known in the art that expandable cuffs have the same pressure prevailing throughout the cuff, as they are the same concept as a typical balloon.

Regarding claim 17, Bronson et al. teaches that the part of the cuff that, in the inflated state, is located in the pharynx has a wedge-like shape with a greater volume proximally than distally, such that this part of the cuff located in the pharynx, in the inflated state, pushes the respirator towards the oesophagus (Fig. 10 shows that cuff 15b has a greater volume than cuff 15a; and both cuffs 15a and 15b push the respirator towards the esophagus).

Regarding claim 18, Bronson et al. teaches a combination of the respirator and a probe (21), such as a stomach tube, duodenum tube or feeding tube, wherein the probe is suitable for insertion through the second tube (see Fig. 10).

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bronson et al. (US Pat. No. 4,327,720) in view of Niklason et al. (US Pat. No. 6,443,156 B1).

Regarding claim 9, it is noted that Bronson et al. does not teach that the interior part of the first and second tube parts are separate from one another as required. However, Niklason et al. teaches an endotracheal tube with double lumens (see Fig. 3A). Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Bronson et al. with the feature of the interior part of the first and second tube parts are separate from one another as taught by Niklason et al., as both Bronson et al. and Niklason et al. are directed to the respirator for a person or animal. The rationale to modify the device of Bronson et al. with the double lumen system is to prevent the contents of the first and second tube parts from possible mixing.

11. Claims 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bronson et al. (US Pat. No. 4,327,720) in view of O'Neil (US Pat. No. 5,865,176).

Regarding claim 10, it is noted that Bronson et al. does not specifically teach that the inside of the second tube part has a non-circular cross-sectional shape, such as an oval crosssectional shape as required. However, O'Neil teaches that such feature of a tube having a non-circular cross-sectional shape (see tube 52 in Fig. 3) is old and well known. Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Bronson et al. with the feature of the inside of the second tube part has a non-circular cross-sectional shape, such as an oval crosssectional shape as taught by O'Neil, as both Bronson et al. and O'Neil are directed to the respirator for a person or animal. The rationale

to modify the device of Bronson et al. is to provide a tube shape that can accommodate similar probe tube shapes.

Regarding claim 15, Bronson et al. teaches that the tube assembly has a curved shape (see Fig. 10). It is noted that Bronson et al. does not specifically teach that the distal orifice of the first tube part, viewed in the radial direction, is provided on the inside of the second tube part as required. However, O'Neil teaches that such feature of an aperture (20) at the distal end of a tube (14) that, when viewed in the radial direction, is provided on the inside of the second tube part (32) is old and well known. Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Bronson et al. with the feature of the distal orifice of the first tube part, viewed in the radial direction, is provided on the inside of the second tube part as taught by O'Neil, as both Bronson et al. and O'Neil are directed to the respirator for a person or animal. The rationale to modify the device of Bronson et al. is to provide an alternative way for the first tube part to communicate with the trachea of a patient.

12. Claim 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bronson et al. (US Pat. No. 4,327,720) in view of Brain (US Pat. No. 5,682,880).

Regarding claim 12, it is noted that Bronson et al. does not explicitly teach that a flexible stiffener that extends as far as the tip of the distal part of the cuff is provided in the distal part of the cuff as required. However, Brain teaches that such feature of a laryngeal mask airway with a guide passage (20) and stiffener (21) that helps install the device in a patient is old and well known. Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Bronson et al. with the feature of the flexible

stiffener that extends as far as the tip of the distal part of the cuff is provided in the distal part of the cuff as taught by Brain, as both Bronson et al. and Brain are directed to the respirator for a person or animal. The rationale to include the guide passage and stiffener in the device of Bronson et al. is to provide for easy patient intubation.

Regarding claim 13, it is noted that Bronson et al. does not explicitly teach that the second tube part runs through the flexible stiffener as required. However, Fig. 1 of Brain teaches that such feature of a guide passage (20) and stiffener (21) that lie on the outside of an airway tube (10) is old and well known. Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Bronson et al. with the feature of the second tube part runs through the flexible stiffener as taught by Brain, as both Bronson et al. and Brain are directed to the respirator for a person or animal. The rationale to include the guide passage and stiffener in the device of Bronson et al. is to provide for easy patient intubation.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Young (US Pat. No. 4,230,108) teaches a flexible esophageal tube with inflatable cuffs fixed below and above the tracheal entrance.

Don Michael (US Pat. No. 5,339,808) teaches an intubation device composed of multiple hollow tubes with inflatable cuffs that can be inserted into the patient's trachea or esophagus.

Dragisic (US Pat. No. 6,536,437 B1) teaches an airway system with a flexible tube and a single inflatable cuff with distal and proximal ends.

14. Any inquiry Regarding this communication or earlier communications from the examiner should be directed to KAIYEU CHU whose telephone number is (571)270-5376. The examiner can normally be reached on Monday-Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe H. Cheng can be reached on 571-272-4433. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. C./
11/09/2009

/Joe H Cheng/
Supervisory Patent Examiner
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